Additional Elements That May Be Included in the Consent Form

Disclosure of data from research testing

When applicable, one or more of the following elements of information shall also be provided to each participant:

- Disclosure or non-disclosure of particular studies presented in the planned project. For example, the informed consent for a research study might advise patients in the following way: Over the course of this trial, routine healthcare information, such as [name of test] results and standard blood tests, will be obtained and kept in your medical record.

  > The results of these tests may be available to you from your healthcare provider. In addition, trial investigators may collect certain data that are not routine healthcare information, including [for example, assay results name of tests]; these are new [definition] of uncertain significance. The results of these tests will not be released to you.

- Special considerations for children should be addressed explicitly with language such as “parent or legally authorized representative has a right to look at the child’s data.”
- Most research data derived from tissue specimens has not been validated for clinical decision-making and should not be disclosed to the participant under most circumstances. In contrast, aggregate data should be made available to research participants when appropriate or if requested (Proceedings of the Confidentiality, Data Security and Cancer Research Workshop, Bethesda, MD, December 1-2, 1999).

Current Chapter

07. Informed Consent

Other Sections

Elements and Disclosures of the Informed Consent Process

Future Use Of Biological Specimens Collected Under Clinical Protocols

GINA – Genetic Information Nondiscrimination Act

Requirement to Obtain Signature

Requirement to Use Understandable Language

Requirements for Cooperative Group Studies

Requirements When a Participant or the Legally Authorized Representative is Unable to Read

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